



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited from Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for substances prohibited for use in animal food or feed.

DATES: Submit electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION

CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Prohibited From Use in Animal Food or Feed--21 CFR Part 589 (OMB Control

Number 0910-0627--Revision)

This regulation prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of bovine spongiform encephalopathy (BSE) in United States' cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

Description of Recordkeeping for Respondents: Rendering facilities, medicated feed manufacturers, livestock feeders.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section 589.2001; Substances Prohibited from Use in Animal Food or Feed	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours	Operating and Maintenance Costs
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	\$59,500
589.2001 (c)(2)(ii)	50	1	50	20	1,000	\$17,000
589.2001(c) (3)(i)(A)	175	1	175	26	4,550	\$80,580
Total					9,050	\$157,080

¹There are no capital costs associated with this collection of information.

The number of recordkeepers times the number of records per recordkeeper equals total annual records. Total annual records times average burden per recordkeeper equals total hours.

Description of Respondents for Reporting: The final regulation on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed. A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the country's BSE status (§589.2001(f)). During the past 6 years, FDA received 2 requests from countries to be exempted from CMPAF restrictions.

FDA estimates the reporting burden for this information collection as follows:

Table 2.--Estimated Annual Reporting Burden¹

21 CFR Section 589.2001(f)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Respondent	Total Hours
One-time (initial) burden	1	1	1	80	80
Burden from future review	1	1	1	26	26

¹There are no capital costs or operating costs associated with the collection of information.

One-Time (initial) Reporting Burden

There will be a one-time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to CMPAF. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 2 row 1 presents the one-time burden for the exclusion. (See final BSE regulation at 73 FR 22754).

Recurring Burden

Countries that successfully petition FDA to be designated as exempt from certain BSE-related restrictions applicable to animal feed will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 2 row 2 presents the expected recurring burden.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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